APR - 3 2001 K003986

Attachment 1: 510(k) Summary:

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: B-K Medical A/S
Address: Sandtoften9, DK2820Gentofte, Denmark
Phone: +45 45970100
Fax: +45 45970199
Contact person: Villy Braender, Quality Assurance Mnager
Date prepared: 21. December , 2000

Trade name: Ultrasound Scanner Type 2102
Common name: Diagnostic Ultrasound System
Classification names:

Ultrasonic Pulsed Echo Imaging System	(90 IYO, CFR 892.1560)
Ultrasonic Pulsed Doppler Imaging System	(90 IYN, CFR 892.1560)
Diagnostic Ultrasonic Transducer	(90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:
Siemens Medical Systems: Sonoline 7XX Diagnostic Ultrasound System (K992046)

Device description:

2102 supports the following scanning modes and combinations thereof:
B-mode, M-mode, Color Doppler, PW Doppler mode. Harmonic Imaging.
An optional ECG signal can be superimposed the ultrasound information in all modes and mode combinations.
The system can perform simple geometric measurements, and perform calculations in the areas of Urology, Cardiology and OB/GYN applications.
The system can guide biopsy- and puncture needles.

Transducers
Transducers are linear and convex arrays and mechanical sector.
The patient contact materials comply with ISO10993-1
All transducers used together with 2102 are Track 3 transducers.

Acoustic output
The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta ≤ 720 mW/cm² and MI ≤ 1.9 (Track 3, non ophthalmic).
The Thermal Index values are maximum 6.0, i.e. TI ≤ 6.0

Clinical measurement accuracy.
Clinical measurements and calculations are described and accuracies are provided in the User Guide.

Thermal, mechanical and electrical safety.
The scanner 2102 has been tested by a recognized, certified body according to IEC 60601-1 .

Acoustic Output Reporting

The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 30, 1997"
The acoustic output is measured and calculated according to: "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (AIUM 1998).

Intended use.
Harmonic Imaging does not add new intended uses.
See comparison below

Technological characteristics compared to the predicate device.
The predicate device has the same major technological characteristics as the subject device, see comparison below.

Comparison with K992046, Sonoline 7XX (Siemens Medical Systems).

	Type 2101 in this application	K992046, Sonoline 7XX
Intended uses	Abdominal, Cardiac, Fetal, Intraoperative, Neurosurgery, Obstetrics, Pediatrics, Transrectal, Small organs, Transvaginal, Peripheral Vascular	General Radiology, Abdominal,Intraoperative,Small parts, transcranial,OB/GYN, Pelvic,Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular
General device description	B,M, Color, PW and combination modes, Harmonic Imaging. Track 3 (Index display). Measurements	B,M Color, PW, CW and combination modes. HarmonicImaging. Track 3 (Index display). Measurements.
Acoustic output	Ispta ≤ 720 mW/cm² and MI ≤ 1.9 (Track 3, non ophthalmic). TI ≤ 6.0. Index display according to Display standard	Index display according to Display standard.
General safety and effectiveness	UL2601, CSA22.2 No 601-1, EN60601, 93/42/EEC Medical Devices Directive, AIUM/NEMA Display standard, EN/ISO 10993-1	UL2601, CSA22.2 No 601-1, EN60601,93/42/EEC Medical Devices Directive, AIUM/NEMA Display standard
Labeling	Modified to include harmonic imaging	No info. in 510(k) summary)

Conclusion: The device Type 2102 in this application has intended uses and modes, that are subparts of that of the predicate device. B-K Medical A/S therefore believes, that Type 2102 is substantially equivalent to this predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2001

Mr. Villy Braender
QA Manager
B–K Medical A/S
Sandtoften 9
DK-2820 Gentofte
DENMARK

Re: K003986
Trade Name: Ultrasound Scanner Type 2102 and Transducer
Type 8660 Addition of Tissue Harmonic Imaging
Regulatory Class: II/21 CFR 892.1550/21 CFR 892.1560/21 CFR 892.1570
Product Code: 90 IYN/90 IYO/90 ITX
Dated: March 9, 2001
Received: March 12, 2001

Dear Mr. Braender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducer intended for use with the Ultrasound Scanner Type 2102, as described in your premarket notification:

Transducer Model Number:

8660

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good

Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded. The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2102
Transducer: 8660

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PW D	**Tissue Harmonic Imaging**	Color Doppler	Combined (Specify)	Amp Do
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	P	P	P		P	P 1)	P
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P 1)	P
	Small Organ (Specify)	P	P	P	N	P	P 1)	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	P	P	N	P	P 1)	P
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Intraoperative: Breast, liver, pancreas, biliary system
Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes
1) mode combinations: B, B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
Radiological Devices
) Number K003986